

JUL 11 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k123343

Company / Contact Person

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Date Prepared

October 24, 2012

Regulatory Declarations

| | |
|---------------------------|--|
| Common / Usual Name | QMS® Tacrolimus Immunoassay |
| Trade / Proprietary Name | Thermo Scientific QMS® Tacrolimus Immunoassay Thermo Scientific QMS® Tacrolimus Calibrators |
| Classification Regulation | 21 CFR 862.1678, Tacrolimus Test System 21 CFR 862. 1150, Calibrator |
| Device Class | Class II |
| Device Regulation Panel | Clinical Chemistry |
| Product Code | MLM, JIT |

Intended Use

QMS® Tacrolimus Immunoassay

The QMS® Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This *in vitro* diagnostic device is intended for clinical laboratory use only.

QMS® Tacrolimus Calibrators

The QMS® Tacrolimus Calibrator set is intended for use in calibration of the QMS® Tacrolimus Immunoassay.

Legally Marketed Device to Which Equivalency is Claimed

The Thermo Scientific QMS® Tacrolimus Immunoassay is substantially equivalent to the previously cleared Abbott ARCHITECT® Tacrolimus Assay (k070820).

Device Description

The QMS® Tacrolimus Immunoassay consists of separately packaged reagents (Reagent 1, Reagent 2 and Extraction Reagent) and calibrators (Calibrator A, B, C, D, E, and F).

1. Reagent Kit Contents and Configurations

| Component | Description | Configuration |
|--------------------------------------|--|---------------|
| Reagent 1 (Antibody Reagent) | <1.0% Anti-Tacrolimus monoclonal antibody (rabbit) in a buffer as stabilizer and <0.09% sodium azide as preservative | 1 x 18 mL |
| Reagent 2 (Microparticle Reagent) | <0.3% Tacrolimus-coated microparticles in buffer containing <0.09% sodium azide as preservative | 1 x 12 mL |
| Extraction Reagent | 300 mM Zinc Sulfate and <0.09% sodium azide as preservative | 1 x 50 mL |

QMS® Tacrolimus Reagents are provided ready-to-use in liquid form and are to be stored at 2 to 8°C until the expiration date on the label.

2. Calibrator Kit Contents and Configurations

| Calibrator Level | Target Concentration (ng/mL) | Configuration |
|------------------|------------------------------|---------------|
| Calibrator A | 0.0 | 1 x 4 mL |
| Calibrator B | 2.0 | 1 x 2 mL |
| Calibrator C | 5.0 | 1 x 2 mL |
| Calibrator D | 10.0 | 1 x 2 mL |
| Calibrator E | 20.0 | 1 x 2 mL |
| Calibrator F | 30.0 | 1 x 2 mL |

The QMS® Tacrolimus Calibrator kit is provided separately and packaged in amber glass bottles in a rectangular cardboard box with a 6-bottle divider. The calibrators are provided in liquid form and are to be stored at -20°C ± 5°C until the expiration date on the label. They are ready-to-use upon thawing.

Comparison of Technological Characteristics

| Comparison | Proposed Device | Predicate Device |
|---------------------------|---|--|
| Proprietary Name | Thermo Scientific QMS® Tacrolimus Immunoassay | Abbott ARCHITECT® Tacrolimus Assay (k070820) |
| Intended Use | The QMS® Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This <i>in vitro</i> diagnostic device is intended for clinical laboratory use only. | The ARCHITECT Tacrolimus assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of tacrolimus in human whole blood on the ARCHITECT i System. The ARCHITECT Tacrolimus assay is to be used as an aid in the management of liver and kidney allograft patients receiving tacrolimus therapy. |
| Test Principle | The QMS® Tacrolimus Immunoassay is a homogeneous particle-enhanced turbidimetric inhibition immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the tacrolimus antibody reagent. The tacrolimus-coated microparticle reagent is rapidly agglutinated in the presence of the anti-tacrolimus antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically. When a sample containing tacrolimus is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained with the maximum rate of agglutination at the lowest tacrolimus concentration and the lowest agglutination rate at the highest tacrolimus concentration. | The ARCHITECT Tacrolimus assay is a delayed one-step immunoassay for the quantitative determination of tacrolimus in human whole blood using CMIA technology with flexible assay protocols, referred to as Chemiflex. Prior to the initiation of the automated ARCHITECT sequence, a manual pretreatment step is performed in which the whole blood sample is extracted with a precipitation reagent and centrifuged. The supernatant is decanted into a Transplant Pretreatment Tube, which is placed onto the ARCHITECT® System. Sample, assay diluent, and anti-tacrolimus coated paramagnetic microparticles are combined to create a reaction mixture. Tacrolimus present in the sample binds to the anti-tacrolimus coated microparticles. After a delay, tacrolimus acridinium-labeled conjugate is added to the reaction mixture. The tacrolimus on the acridinium-labeled conjugate competes for the available binding sites on the microparticles. Following incubation, the microparticles are washed, and pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of tacrolimus in the sample and the RLUs detected by the ARCHITECT® System optics. |
| Sample Matrix | Human Whole Blood | Human Whole Blood |
| Sample Preparation | Manual Pretreatment | Manual Pretreatment |
| Reagent | Liquid Ready-to-Use (Antibody reagent, Tacrolimus coated microparticle reagent, and Extraction reagent) | Liquid Ready-to-Use (Antibody coated microparticle reagent, Tacrolimus conjugate reagent, and Assay diluent) |
| Calibrator | Liquid Ready-to-Use, six levels (0.0, 2.0, 5.0, 10.0, 20.0, and 30.0 ng/mL) | Liquid Ready-to-Use, six levels (0.0, 3.0, 6.0, 12.0, 20.0, and 30.0 ng/mL) |
| Assay Range | 1.0 to 30.0 ng/mL | 2.0 to 30.0 ng/mL |

Summary of Performance Testing

Functional Sensitivity (LOQ)

The Functional Sensitivity or Limit of Quantitation (LOQ) of the assay is defined as the lowest concentration that will demonstrate a Coefficient of Variance (CV) of inter assay precision at 20% that has been measured over an extended period. The Functional Sensitivity or LOQ is 0.9 ng/mL.

Precision

The total-run precision of the QMS® Tacrolimus Immunoassay at various levels across the assay range was determined to be less than or equal to 7.3% CV.

Dilution Recovery

Samples were tested to demonstrate linearity throughout the assay range. The assay is linear from 0.8 to 29.9 ng/mL.

Spike Recovery

Samples were tested to verify the recovery of analyte across the dynamic range of the assay. The recovery for all samples were less than or equal to 10% error.

Method Comparison

Samples were tested in the QMS® Tacrolimus Immunoassay and compared to reference method LC-MS/MS and predicate device Abbott ARCHITECT® Tacrolimus assay. The method comparison between the QMS® Tacrolimus Immunoassay and LC-MS/MS is $y = 1.111x + 0.53$, $R = 0.972$. The method comparison between the QMS® Tacrolimus Immunoassay and Abbott ARCHITECT® Tacrolimus assay is $y = 1.126x - 0.03$, $R = 0.937$.

Specificity

Specificity studies were conducted for available major metabolites of tacrolimus, medications routinely co-administered with tacrolimus, and other over-the-counter drugs. The studies indicate the QMS® Tacrolimus Immunoassay has partial cross reactivity to major metabolites and minimal to no cross reactivity for co-administered and over-the-counter drugs.

Interfering Substances

Endogenous substances that commonly exist in human whole blood were tested to ensure no interference with the quantitation of tacrolimus using the QMS® Tacrolimus Immunoassay. At the concentrations tested, the interfering substances caused less than 10% error with the QMS® Tacrolimus Immunoassay.

Reagent Stability

The reagents for the QMS® Tacrolimus Immunoassay were tested for real time and accelerated time stability. The reagents are stable for up to 13 months at 2-8°C based on accelerated studies. The on-board reagent stability is stable for up to 35 days on the Beckman AU680® clinical analyzer.

Calibrator Stability

The calibrators for the QMS® Tacrolimus Immunoassay were tested for real time and accelerated time stability. The calibrators are stable for up to 15 months at -20°C based on accelerated studies. The calibrator open vial stability is stable for 42 days at 2-8°C when stored tightly capped.

Conclusion

Substantial equivalence of the QMS® Tacrolimus Immunoassay to the previously cleared Abbott ARCHITECT® Tacrolimus Assay has been demonstrated through performance testing (Section 18) to verify that the device functions as intended and design specifications have been satisfied.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 11, 2013

Microgenics Corp.
C/O Karen Lee
46360 Fremont Blvd.
FREMONT CA 94538

Re: K123343

Trade/Device Name: Thermo Scientific QMS® Tacrolimus Immunoassay
Thermo Scientific QMS® Tacrolimus Calibrators

Regulation Number: 21 CFR 862.1678

Regulation Name: Tacrolimus test system

Regulatory Class: II

Product Code: MLM, JIT

Dated: June 18, 2013

Received: June 20, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2—Ms. Lee

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123343

Device Name: Thermo Scientific QMS® Tacrolimus Immunoassay
Thermo Scientific QMS® Tacrolimus Calibrators

Indications for Use:

QMS® Tacrolimus Immunoassay

The QMS® Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This in vitro diagnostic device is intended for clinical laboratory use only.

QMS® Tacrolimus Calibrators

The QMS® Tacrolimus Calibrator set is intended for use in calibration of the QMS® Tacrolimus Immunoassay.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.07.10 07:27:22 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123343